

R E M A R K S

Claims 1-3, 7, and 9 are pending and under examination. The claims have been rejected under 35 U.S.C. 103 as obvious over Cook et al. (US Pat. No. 5,554,646) in view of Kawamura et al. (Hypertension 27:408-413 (1996)). The Examiner states that Cook et al. discloses a method of reducing body fat by administering CLA. The Examiner admits that Cook et al. does not teach the use of CLA to treat hypertension. The Examiner states that Kawamura et al. teach that reduction in body weight in overweight human patients correlates to a reduction in hypertension and that this provides a “nexus teaching between hypertension, weight loss and decreases in blood pressure.” Office Action at p. 3.

Applicant's respectfully submit that the Examiner has not established a *prima facie* case of obviousness. A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims at issue.¹ The claims are not obvious because the cited references do not provide a motivation to combine and do not provide a reasonable expectation of success.

1. No Motivation to Combine

The Examiner argues that one would be motivated to use CLA to treat hypertension “because Cook et al. provide a method of reducing body fat and Kawamura et al. teach that reduction in weight in hypertensive patients results in a lowering of blood pressure. Thus the method of Cook et al. is beneficial to the instantly claimed patient population and would have been obvious to one of ordinary skill in the art.” Office Action at p. 4. A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**²

Applicants respectfully submit that the Examiner's motivation to combine does not meet this standard. The Examiner's basic argument is that because CLA has been used to reduce body weight and that because reduction of body weight in overweight patients can lead to reduction in hypertension, that the two cited references can be combined. However, this reasoning completely ignores that CLA is a biologically active agent and, as such, could have either a positive or negative effect on hypertension independent of its effect on weight loss. In other words, just because CLA can induce weight loss does not mean that it will have a positive or negative effect on hypertension. The Examiner's argument is without scientific merit. Indeed, one need look no further than the example ephedrine, a commonly used, biologically active weight loss supplement. As established in Haller and Benowitz, Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids, New England J. Med. 343(25):1833-1838 (2000)(attached hereto as appendix 1), ephedrine can cause an increase in hypertension. According to the Examiner's argument, it would be obvious to use any weight loss supplement to decrease hypertension. However, clearly this is not the case because some biologically active weight loss agents cause increases in hypertension.

Thus, there is no motivation to combine references concerning the reduction of hypertension by weight loss due to dieting and the reduction of body weight by using a biologically active dietary supplement. There is no correlation between these two independent observations. One of skill in the art would recognize that the mechanisms of weight loss through use of a biologically active dietary supplement and through simply dieting as taught in Karamura are most likely to be **completely distinct**. Thus, the person of skill in the art would not make the combination suggested by the Examiner.

2. No Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed methods. The Federal Circuit has held that "obvious to experiment" is not the standard

² See, *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

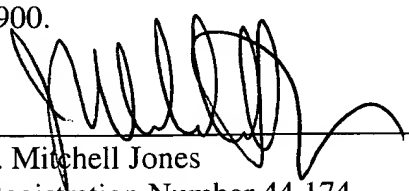
for obviousness. *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988). The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added).

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for arriving at the claimed invention. As detailed above, just because a biologically active substance causes weight loss does not mean that the substance will or will not treat hypertension or cause hypertension. Empirical experimentation is required to determine if the biologically active substance will be antihypertensive or prohypertensive. Again, one need look no further than the fact that ephedrine, a substance known to useful for causing weight loss, causes hypertension. There is no way to predict whether a given agent will cause hypertension, prevent hypertension, or be nonactive with respect to hypertension without testing the substance. Not all agents that cause weight loss cause a reduction in hypertension. Thus, there was no likelihood of success in using CLA to treat hypertension.

CONCLUSION

It is respectfully submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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J. Mitchell Jones
Registration Number 44,174
MEDLEN & CARROLL, LLP
101 Howard St., Suite 350
San Francisco, California 94105

APPENDIX 1